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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,749	01/14/2002	Michael Vajdy	16464.003	5494

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CHIRON CORPORATION  
Intellectual Property - R440  
P.O. Box 8097  
Emeryville, CA 94662-8097

EXAMINER

BROWN, TIMOTHY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/051,749

Applicant(s)

VAJDY ET AL.

Examiner

Tim Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-21, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Non-Final Office Action is responsive to Applicants' Election mailed April 1, 2004. Applicants' election to prosecute the invention of Group II has been acknowledged. Applicants' election of the following species is also acknowledged: HIV, a viral vector, an alphaviral vector, and class I and/or class II MHC proteins. Claims 1-5, 8-21, 29 and 30 are therefore pending. Claims 6, 7 and 22-28 are withdrawn from consideration.

Applicants traverse the restriction requirement on several grounds. First, Applicants argue examining each of the groups would not require impose an undue burden on the Examiner. Applicants reason that because each of the groups ultimately incorporates claim 1, a search of claim 1 would necessarily reveal art for each of the identified groups. This would be true if the claims were directed to nothing more than a method for generating an immune response using a gene delivery vehicle. However, the claims are directed to several patentably distinct embodiments of the method of claim 1. For example, the search for a method of generating an immune response against a sexually transmitted bacteria (Group I), will not find art for the same method as applied to a virus (Group II). This results because each method would **necessarily** involve different antigens having distinct compositions and shapes. Accordingly, requiring a search of each of the patentably distinct groups invention would unduly burden on the Examiner.

Applicants also traverse the restriction on the ground that the Office Action does not adequately define the species of the viral vector. Applicants note the Office Action

did not list all species of the viral vector, including the claimed alphavirus vector.

However, Applicants responded to the restriction requirement by electing the alphavirus vector. Thus, the restriction requirement provided adequate clarity for Applicant's to make a meaningful response. Moreover, supplementing the Restriction Requirement by listing the specific species of viral vector would be moot in view of Applicants' election.

The Office Action clearly explains why each species of viral vector is patentably distinct. The Office Action explained that viral vectors are distinct because "each vector elicits a different immune response, has a specificity for different tissues and expresses antigens differently." This reasoning would apply to each species of viral vector regardless of whether it is listed in the Office Action. The Office Action therefore provides adequate reasoning for the restriction between viral vectors.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-5, 8-14, 16-20, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Malone et al. (U.S. Pat. No. 6,110,898) ("Malone").**

Applicants' invention is drawn to a method of inducing mucosal immunity by administering an antigenic polynucleotide to the mucosal surfaces of a subject. The

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antigenic polynucleotide encodes an antigen from a sexually transmitted disease. The invention administers the polynucleotide using an alphavirus vector that may take the form of a replicon. The alphavirus vector further comprises a Sinbis virus and an HIV-1 antigen. According to the invention, the polynucleotide is introduced to the vaginal, rectal and nasal mucosal surfaces. The polynucleotide is delivered to antigen presenting dendritic cells.

Malone anticipates Applicants' invention because it discloses a method of inducing a mucosal immune response wherein an antigenic polynucleotide is administered to the vaginal, nasal or rectal mucosal membranes of a subject (abstract, lines 2-4; col. 14, lines 64-66; col. 15, lines 57-62; and col. 17, lines 61-63). Malone's antigenic polynucleotide may be derived from a sexually transmitted virus such as HIV-1 (col. 20, lines 7-10 and 23-25). Malone further provides that the polynucleotide is delivered by an alphaviral vector such as Sinbis or Semliki Forest virus (col. 11, lines 39-41). Malone's alphaviral vector comprises a replicon (col. 2, line 66-col. 3, line 1).

Note that Malone inherently discloses presenting an antigenic polynucleotide to dendritic cells. This results because mucosal membranes are a natural environment for dendritic cells. Thus, by introducing an antigenic polynucleotide to a mucosal surface, Malone necessarily discloses presenting the antigenic polynucleotide to dendritic cells.

Malone also teaches eliciting an HLA class I or HLA class II response through inherency. This results because Malone administers the antigenic polynucleotide to a human (col. 15, line 52). Causing a human to express the antigenic polynucleotide

would necessarily result in an HLA class I and HLA class II response. Malone therefore discloses an HLA class I or HLA class II response through inherency.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malone in view of Parker et al. (U.S. Pat. No. 6,261,570) ("Parker").**

Malone teaches the method of inducing a mucosal immune response as noted above. Malone does not expressly teach "wherein said alphavirus vector comprises elements from two or more alphaviruses." However, Parker discloses vaccines directed against numerous alphavirus pathogens including Western Encephalitis virus, Eastern Encephalitis virus and Venezuelan Encephalitis virus (abstract, lines 1-4). Parker also discloses expressing antigens of other alphaviruses as chimeric alphaviruses for use as potential vaccines for humans (col. 5, lines 39-51). The knowledge generally available to the skilled artisan appreciates that an alphaviral vector may be modified with other antigenic sequences to achieve immunity against a desired pathogen. Therefore, at the time of Applicants' invention, it would have been obvious to one of ordinary skill in the art to modify Malone to include the teachings of Parker as this combination would provide a method for inducing musocal immunity against a variety of alphaviral pathogens.

**Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malone in view of De Plaen et al. (U.S. Pat. No. 5,612,201) ("De Plaen").**

Claim 21 is drawn to introducing a nucleic acid encoding either MHC-I or MHC-II into the target cells prior, or subsequent to, the administration of the antigenic polynucleotide. While Malone teaches the method of inducing mucosal immunity noted above, it does not expressly teach introducing either a MHC-I or MHC-II sequence as claimed. However, De Plaen teaches administering a MHC sequence to a target cell prior to transformation of the target cell. De Plaen explains that the advantage of this procedure is to enhance the immunoreactive response of the targeted cell (see col. 33, lines 6-19). Therefore, at the time of Applicants' invention, it would have been obvious to one of ordinary skill in the art, to modify Malone to include the teachings of De Plaen since this combination would improve the immunogenicity of Malone's method of mucosal immunization.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown  
Examiner  
Art Unit 1648

tmb



7/12/04

JAMES HOUSEL  
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